K073285

MAY 15 2008

**MEDTRONIC Sofamor Danek**
**PEEK PREVAIL™ Cervical Interbody Device**
**February 2008**

I. **Company:** Medtronic Sofamor Danek, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
(901) 396-3133

II. **Product Name:** PEEK PREVAIL™ Cervical Interbody Device
**Common Name:** Interbody Fusion Device
**Classification:** 21 CFR 888.3080 – Product Code: MAX, ODP

III. **Description**: The PEEK PREVAIL™ Cervical Interbody Device is an intervertebral body fusion device with internal screw fixation. The screws protrude through the interbody portion of the device and stabilize the vertebral body while preventing expulsion of the implant. The implant is "I-Beam" shaped with a 2 screw midline configuration. This device is intended to be radiolucent and the interior space of the product is to be used with autograft.

The PEEK PREVAIL™ Cervical Interbody device implant is manufactured from PEEK Optima® and contains tantalum radiopaque markers and a Nitinol screw locking mechanism. The screws used with this device (ZEPHIR® Anterior Cervical Screws) are manufactured from Titanium Alloy.

IV. **Indications for Use:** The PEEK PREVAIL™ Cervical Interbody Device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The PEEK PREVAIL™ Cervical Interbody Device must be used with internal screw fixation provided by ZEPHIR® Anterior Cervical Screws. The PEEK PREVAIL™ Cervical Interbody Device implants are to be used with autograft and implanted via an open, anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

V. **Substantial Equivalence:** Documentation was provided which demonstrated that the PEEK PREVAIL™ Cervical Interbody Device components are substantially equivalent to previously approved devices such as the previously approved AFFINITY® Anterior Cervical Cage (P000028, Approved - 06/13/2002), the BAK/C® Cervical Interbody Fusion System (P980048, Approved – 04/20/2001), VERTE-STACK® Spinal System (K070173, S.E. 3-14-2007 and K062073, S.E. 8-14-2007), and the VENTURE™ Anterior Cervical Plate System (K061274, S.E. 05-25-2006).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek, Inc.
% Mr. Michael Scott
1800 Pyramid Place
Memphis, TN 38132

SEP 12 2011

Re: K073285
Trade/Device Name: PEEK PREVAIL™ Cervical Interbody Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: May 7, 2008
Received: May 9, 2008

Dear Mr. Scott:

This letter corrects our substantially equivalent letter of May 15, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not

limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

November 2007

510(k) Number (if known): K073285

Device Name: PEEK PREVAIL™ Cervical Interbody Device

**Indications for Use:**

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for MKM

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K073285